K122501

510(k) Summary

MAR 2 9 2013

DATE: August 10, 2012

510(k) SPONSOR: American Eagle Instruments, Inc
6575 Butler Creek Road
Missoula, MT 59808

CONTACT PERSON: Kristen Nsytuen
Compliance Manager/Engineer
(406) 549-7451
knystuen@am-eagle.com

TRADE NAME: AEI (Dr. Terauchi) Ultrasonic Tips

COMMON NAMES: Ultrasonic Tips

CLASSIFICATION, and CLASS: 21 CFR 872.4850, Class II;

PRODUCT CODES: ELC

PREDICATE DEVICE:

Company	Device	510(k) No.	Date Cleared
DENTSPLY	ProUltra® Endo Tips *(a.k.a Sapphire Plus® Tips)*	K960889	May 10, 1996

DEVICE DESCRIPTION: The AEI Ultrasonic Tips are an accessory to a Piezo ultrasonic hand piece and unit. These external power supplies are not part of the device submitted for application with the 510(k) submission. The Ultrasonic Tips with a concave spoon shape or straight tip are very small and will not cut significant amounts of dentin during use. The AEI Ultrasonic Tips will be available in M3x0.6 thread with 5 different types of tip design to facilitate reaching specific angles and directions in the root of the tooth.

INDICATIONS FOR USE: The AEI Ultrasonic Tips are intended for use by dental professionals for endodontic root preparation procedures. The Ultrasonic Tips can remove soft and hard tissue from a narrow dentinal structure in order to make space for permanent filling material in the canal. They can also assist in the removal of separated instruments or other intra-canal blockages.

SUMMARY OF TECHNOLOGIES/SUBSTANTIAL EQUIVALENCE:

A comparison of the AEI Ultrasonic Tips and the currently marketed ProUltra® Endo Tips indicates the following similarities to the device which received 510(k) clearance:

* Same technological characteristics
* Same operating principle
* Similar design features
* Same connection capabilities to piezoelectric ultrasonic generator
* Same material

NON-CLINICAL TESTING:

Substantial equivalence of the AEI Ultrasonic Tips to the predicate device is based on a comparison of indications, intended use and materials. Mechanical testing was, therefore, not conducted.

CLINICAL TESTING:

Clinical evaluations were conducted outside the US and showed that the devices were safe and effective for the proposed indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 29, 2013

Ms. Kristen Nystuen
Compliance Manager/Management Representative
American Eagle Instruments, Incorporated
6575 Butler Creek Road
MISSOULA MT 59808

Re: K122501
Trade/Device Name: AEI Dr. Terauchi Ultrasonic Tips™
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: February 18, 2013
Received: February 26, 2013

Dear Ms. Nystuen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for
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Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122501

Device Name: AEI Dr. Terauchi Ultrasonic Tips™

The AEI Dr. Terauchi Ultrasonic Tips are intended for use by dental professionals for endodontic root preparation procedures. The Ultrasonic Tips can remove soft and hard tissue from a narrow dentinal structure in order to make space for permanent filling material in the canal. They can also assist in the removal of separated instruments or other intra-canal blockages.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MA Mary S. Runner -S 2013.03.22 12:24:07 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122501